REMARKS

Claims 1-4 and 7-11 stand rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,746,468 to Sepetka et al. Claims 1, 2, 5, 7-9 and 12 stand rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,547,804 to Porter et al. Claims 1, 6, 7-9 and 13 stand rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 6,146,396 to Konya.

In the amendment presented above, Applicant has amended independent claims 1, 7 and 13 to further define the invention of the cited prior art. Applicant has also added new dependent claims 14-24. Applicant respectfully submits that the present invention as recited in the amended claims is neither taught nor suggested by the cited prior art.

More particularly, claim 1 as amended recites, *inter alia*,

> a plug for insertion along the longitudinal axis into the lumen of the blood vessel, the plug having a tapered outer surface and a large diameter section with a cross-sectional diameter greater than the interior diameter of the lumen of the inner wall [of the blood vessel] such that the plug is gripped by compressive forces exerted by the elastic nature of the inner wall of the blood vessel and thereby occludes blood flow through the lumen of the blood vessel ....

Nowhere do the cited prior art references teach or suggest these features.

The apparatus in Sepetka et al. includes an expandable device 4 (fiber mesh structure) which is delivered through vessel lumen(s) to an aneurysm and expanded

therein to partially fill the aneurysm. The aneurysm is reduced in size so that expandable structure supports and reinforces the body and neck of the aneurysm wall (Fig. 6). The aneurysm is reduced in size by heating the aneurysm wall (by RF energy applied thereto by the device 4) or by chemical action. A sealant may be introduced into the aneurysm to seal it.

The apparatus of Porter et al. includes a porous occlusion balloon 22 detachably mounted to the distal end of a catheter. The balloon 22 is positioned within an aneurysm 25 and inflated with an aqueous inflation fluid (e.g., saline or blood plasma and/or contrast agent). Once the location is confirmed, a solidifying fluid is injected into the porous balloon thereby displacing the inflation fluid. A third fluid is then injected into the balloon under very low additional pressure until the aneurysm has been substantially filled by the balloon such that the balloon does not distort the aneurysm wall and instead conforms itself to the aneurysm morphology (Figs. 2-6).

The apparatus of Konya et al. includes a deformable jacket 16 (e.g., stainless steel mesh) that is deployed and then expanded or contracted via manipulation of a catheter system. The expansion of the deformable jacket 16 allows for maceration of clots and for de-clotting of a site.

Importantly, there are significant differences between the plug of the present invention and the prior art. First, the prior art devices are securely located in a different part of the vascular system than the claimed plug and/or the prior art devices perform

different functions that the claimed plug. More particularly, the claimed plug is held in place within a vessel lumen, and operates to block the flow of blood through the vessel lumen. In contrast, the expandable device 4 of Sepetka and the balloon of Porter et al. are both inserted into an aneurysm. **The aneurysm is not part of the vessel lumen**; it is an enlargement of the vessel that protrudes radially outward like a balloon from the wall of the vessel. Thus, the devices of Sepetka and Porter et al do not occlude the flow of blood through the lumen of the blood vessel, yet support and reinforce the body and neck of the aneurysm wall. The deformable jacket 16 of Porter et al. is positioned within the vessel lumen; however this deformable jacket 16 is expanded and contracted to macerate clots and for de-clotting of a site. It is not used to occlude a vessel lumen.

Second, there are significant differences regarding how these devices are secured in place as compared to the claimed plug. The claimed plug includes a **large diameter section with a cross-sectional diameter greater than the interior diameter of the lumen of the inner wall of the blood vessel) such that plug is gripped by compressive forces exerted by the elastic nature of the inner wall of the blood vessel.** In contrast, the expandable device 4 of Sepetka is maintained at a smaller diameter than the lumen of the vessel through which it travels. After expansion, it is maintained at a size that is smaller than the neck of aneurysm. The aneurysm is shrunk in size to fit around the device. Thus, the expandable device 4 is not gripped by compressive forces exerted by the elastic nature of the inner wall of a vessel, but by shrinking of the aneurysm wall. Similarly, the balloon device of Porter is filled to a level that does not distort the aneurysm wall and instead conforms itself to the aneurysm morphology. Thus, the

balloon device of Porter is not gripped by compressive forces exerted by the elastic nature of the inner wall of a vessel. The deformable jacket 16 of Konya also fails to teach or suggest these features.

Because of these significant differences, Applicant respectfully submits that independent claim 1 as amended is patentable over the cited prior art. Similar arguments apply to independent claim 7.

Dependent claims 2-6, 8, 10-12, and 14-24 are patentable over the cited prior art for those reasons advanced above with respect to independent claims 1 and 7 from which they respectfully depend and for reciting additional features neither taught nor suggested by the cited prior art. For example, claim 15 recites that "the plug further comprises a plurality of spokes that project rearward and radially outward from within said large diameter section." Claim 16 recites that "said spokes extend radially outward to tips that are spaced apart in an annular fashion at a diameter greater than the cross-sectional diameter of the large diameter section." Nowhere do the cited prior art references teach or suggest these features.

With regard to claim 13, Applicant has amended the claim to clarify that the insertion device inserts **an occlusion plug** into a blood vessel. The Examiner seems to point to Konya (Figs. 8-10) as disclosing these features. This analysis is flawed. First, the insertion device of Konya is used to insert an expandable jacket 16 into a blood vessel for de-clotting purposes. It is not used to occlude the blood vessel. Secondly, Konya

fails to teach or suggest important structural features of the claim. More particularly, the insertion device of claim 13 includes a "needle guard" that surrounds a "needle", wherein "the needle fits into a pilot hole of the occlusion plug." The insertion device of Konya does not include these features. Because of these significant differences, Applicant respectfully submits that independent claim 13 as amended is patentable over the cited prior art.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,

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